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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,636	03/31/2005	Hans-Ulrich Petereit	268018US0PCT	1376

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EXAMINER	
EBERHARD, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
12/03/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/529,636	PETEREIT ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Eberhard, Ph.D.	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/31/2005 and 7/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The information disclosure statement filed 3/31/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has only been considered to the extent made possible by Examiner's machine assisted reading of the German language Abstracts.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. In order to perfect the priority, a certified English translation of the German language priority document must be submitted.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The means for mixing of incompatible polymers, critical or essential to

the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim 1 is drawn to a method for producing a pharmaceutical dosage form "...in such a way that the incompatible individual portions are mixed in the spraying process," and claims 2-13 depend either directly or indirectly therefrom. Applicant recites that this incompatibility of the instant acrylate copolymers results in "aggregation or coagulation" (Specification page 3, lines 9-11) such that the "mixture cannot at present be employed industrially in an acceptable manner" (Id. at lines 13-14). The critical steps represented by the phrase "in such a way" are not further elucidated, thus the disclosure is not enabling.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claim 1 is drawn to a method for producing a pharmaceutical dosage form "...in such a way that the incompatible individual portions are mixed in the spraying process," and claims 2-13 depend either directly or indirectly therefrom. The omitted steps describe mixing of the incompatible acrylate copolymers such that aggregation or coagulation is avoided, resulting in an industrially useful process for coating.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claim 12 is rejected under 35 U.S.C. 102(a) as being anticipated by Littman (US 5,254,168).

Littman teaches a fluidized bed coating apparatus comprising two three fluid nozzles suitable for carrying out a method such as instant claim 1 (Abstract and Figure 2). Two individual nozzles of Figure 2 are mounted to form the apparatus of Figure 4 used to coat pharmaceutical products. The nozzle inlets are indicated by structures 32 ("air entry port," column 4, lines 3 and 4), 38 ("jet air inlet," column 4, line 7) and 26/28 ("terminally opposing inlets," column 4, lines 9 and 10) of Figure 2.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishizue (US 5,445,830) in view of Remington in further view of Littman (US 5,254,168).

Ishizue teaches film forming coating agents (*e.g.*, Example 1, column 3, line 60 to column 4, line 50) including aminoalkyl methacrylate ester copolymers (*e.g.* Eudragit® E series, column 2, lines 15-24) and anionic carboxylated methacrylate ester copolymers (*e.g.* Eudragit® L or S series, column 2, lines 15-24) that may be used together in a single formulation to achieve the desired dissolution profile at various gastrointestinal pH's. Ishizue also teaches that the formulations may further comprise plasticizers (column 2, line 60, "excipients for tablet compression"), emulsifiers (column 2, line 32, "surfactants"), and active pharmaceutical ingredients such as anti-hypertensive agents (column 3, line 16). Ishizue does not teach application of the formulated product onto the surface of a core, tablet, or other such dosage form alone or in combination, nor does it teach the spray application recited by Applicant. Ishizue also does not teach relative amounts of the copolymers or excipients in the formulated product.

11. Remington teaches coating of dosage forms (page 1650), including the spray coating of substrates to affect a desired dissolution profile (page 1653 and 1654), and the equipment and procedures to carry out the spray coating operation (page 1655 to 1658). Littman develops this further, teaching an apparatus having multiple spray nozzles. Thus it would have been obvious to the artisan of ordinary skill at the time the invention was made to have combined the two film

forming coating agents (aminoalkyl methacrylate ester copolymers and anionic carboxylated methacrylate ester copolymers) taught by Ishizue with the coating applications and methods taught by Remington and Littman to affect dosage form recited by Applicant.

12. Manipulation of relative amounts of formulation components results in differences in concentration, which will not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating that such concentration data are critical. "[W]here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The adjustment of particular conventional working conditions (*e.g.*, determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ranges recited in claims 1, 3 and 5), as well as affecting the desired dissolution profile, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

It is obvious to the artisan of ordinary skill that combining formulation components taught by Ishizue and dosage form construction taught by Remington can, with routine optimization, result in the dosage form recited in the instant application.

Application Status and Examiner Contact Information

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Eberhard, Ph.D. whose telephone number is (571) 270-3289. The examiner can normally be reached from 7:00 am to 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey S. Eberhard, Ph.D.
Patent Examiner

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